Complete Summary

GUIDELINE TITLE

1) Immunizations. 2) Immunization update.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Immunization update. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007 Dec. 4 p.

Institute for Clinical Systems Improvement (ICSI). Immunizations. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007 Oct. 67 p. [77 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version:

- Institute for Clinical Systems Improvement (ICSI). Immunizations update. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Sep. 4 p. [69 references]
- Institute for Clinical Systems Improvement (ICSI). Immunizations. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Jun. 61 p. [69 references]
- Institute for Clinical Systems Improvement (ICSI). Immunizations. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007 Jan. 8 p.

**** REGULATORY ALERT ****

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- June 15, 2007, RotaTeq (Rotavirus, Live, Oral, Pentavalent Vaccine): Changes to the ADVERSE REACTIONS and POST-MARKETING sections of the product's prescribing information. The ADVERSE REACTIONS section was updated to include six cases of Kawasaki disease that were observed during the Phase 3 clinical trial.

- February 13, 2007, Rotavirus, Live, Oral, Pentavalent Vaccine [RotaTeq]: FDA Public Health Notification regarding 28 post-marketing reports of intussusception following administration of Rotavirus, Live, Oral, Pentavalent vaccine (RotaTeq).

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Diphtheria
- Tetanus
- Pertussis
- Poliomyelitis
- Measles
- Mumps
- Rubella
- Pneumococcal disease
- Varicella
- *Haemophilus influenza b* (Hib) infection
- Hepatitis B (Hep B)
- Influenza
- Hepatitis A (Hep A)
- Meningococcal infection
- Rotavirus infection
- Human papilloma virus (HPV) infection
- Herpes zoster/shingles

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Family Practice
Geriatrics
Infectious Diseases

Internal Medicine
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To increase the rate of people on time with recommended immunizations
- To increase the rate of special groups (pediatrics, adolescents, young adults, adults, seniors) on time with specific antigen immunizations
- To reduce missed opportunities for administering immunizations
- To increase the rate of people who are not on time with recommended immunizations who have a catch-up plan
- To increase the rate of post-immunization serologic testing for appropriate groups

TARGET POPULATION

Persons of all ages in the United States seeking immunity from infectious diseases through the use of vaccines

INTERVENTIONS AND PRACTICES CONSIDERED

1. Routine immunization for infants and children, including:
    - Diphtheria and tetanus toxoids with acellular pertussis (DTaP); tetanus-diphtheria-acellular pertussis vaccine(Tdap)
    - Inactivated poliovirus vaccine (IPV)
    - Measles, mumps, rubella (MMR) or combined measles, mumps, rubella and varicella vaccine (MMRV)
    - Varicella vaccine
    - Pneumococcal 7 valent conjugated polysaccharide vaccine (PCV7)
    - *Haemophilus influenzae b* (Hib) conjugate vaccine, such as HIBTITER (HbOC), ActHIB or OmniHib (PRP-T), Comvax (PRP-OMP), Pedvax (PRP-OMP)
    - Rotavirus vaccine (RotaTeq)
    - Hepatitis B (Hep B) vaccine
    - Hepatitis A (Hep A) vaccine, such as Havrix or Vaqta
    - Meningococcal conjugate vaccine; Meningococcal unconjugated polysaccharide vaccine
    - Influenza vaccine
    - Human papilloma virus (HPV) vaccine
2. Adult immunization, including:

- Tetanus, diphtheria (Td); tetanus-diphtheria-acellular pertussis (Tdap) vaccine
- IPV
- MMR vaccine
- Varicella vaccine
- Influenza vaccine
- Pneumococcal (PPV23) vaccine
- Hepatitis A, such as Twinrix
- Hepatitis B vaccine
- Meningococcal vaccine
- HPV vaccine
- Herpes zoster/shingles (Zostavax®) vaccine

3. Patient/parent education
4. Recording of adverse events
5. Development of systems to track the immunization status of patients

MAJOR OUTCOMES CONSIDERED

- Antibody responses
- Incidence of disease or illness
- Risk of hospitalization and death
- Safety and protective efficacy of vaccinations
- Cost-effectiveness of vaccinations
- Adverse effects of vaccinations

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A literature search of clinical trials, meta-analysis, and systematic reviews is performed.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Conclusion Grades:

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality. Conclusion grades are determined by the work group based on the following definitions:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Guideline Development Process

Each guideline, order set, and protocol is developed by a 6- to 12-member work group that includes physicians, nurses, pharmacists, other healthcare professionals relevant to the topic, along with an Institute for Clinical Systems Improvement (ICSI) staff facilitator. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, 1 or 2 members may be recruited from medical groups or hospitals outside of ICSI.

The work group meets for seven to eight three-hour meetings to develop the guideline. A literature search and review is performed and the work group members, under the coordination of the ICSI staff facilitator, develop the algorithm and write the annotations and footnotes and literature citations.

Once the final draft copy of the guideline is developed, the guideline goes to the ICSI members for critical review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Cost-Effectiveness of Varicella Vaccine

It is cost effective to do immune status testing for all persons 13 years old of age and older, who believe they are nonimmune, before vaccinating. More than 75% of them will be immune. The prevaccination testing will also substantially reduce the average number of needle sticks that patients in this age range need. For most that number will be only one.

Cost-Effectiveness of Tetanus-Diphtheria Booster

A schedule of a single tetanus-diphtheria (Td) booster dose between 50 and 65 years has recently been considered cost effective, but evidence about the adequacy of protection against diphtheria with this approach is currently lacking.

Cost-Effectiveness of Meningococcal Vaccination

Cost-effectiveness ratios of toddler vaccination were essentially equivalent to those of adolescent vaccination. Infant vaccination appeared less cost-effective (median of $482,000 per life-year saved, $1,923,000 per case prevented).

Cost-Effectiveness Human Papillomavirus (HPV) Vaccine

In economic models, the most cost-effective schedule is to routinely immunize all women at ages 11-12 and to do catch-up through age 26. It is not necessary or desirable to test for previous human papillomavirus (HPV) infection when starting the immunization series for sexually active women.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Critical Review Process

Every newly developed guideline or a guideline with significant change is sent to Institute for Clinical Systems Improvement (ICSI) members for Critical Review. The purpose of critical review is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the guideline. Critical review also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes necessary across systems in their organization to implement the guideline.

All member organizations are expected to respond to critical review guidelines. Critical review of guidelines is a criterion for continued membership within ICSI.

After the critical review period, the guideline work group reconvenes to review the comments and make changes, as appropriate. The work group prepares a written response to all comments.

Approval

Each guideline, order set, and protocol is approved by the appropriate steering committee. There is one steering committee each for Respiratory, Cardiovascular, Women's Health, and Preventive Services. The Committee for Evidence-based Practice approves guidelines, order sets, and protocols not associated with a particular category. The steering committees review and approve each guideline based on the following:

- Member comments have been addressed reasonably.
- There is consensus among all ICSI member organizations on the content of the document.
- To the extent of the knowledge of the reviewer, the scientific recommendations within the document are current.
- Either a critical review has been carried out, or to the extent of the knowledge of the reviewer, the changes proposed are sufficiently familiar and sufficiently agreed upon by the users that a new round of critical review is not needed.

Once the guideline, order set, or protocol has been approved, it is posted on the ICSI Web site and released to members for use. Guidelines, order sets, and protocols are reviewed regularly and revised, if warranted.

Document Revision Process

ICSI scientific documents are revised every 12 to 36 months as indicated by changes in clinical practice and literature. Every 6 months, ICSI checks with the work group to determine if there have been changes in the literature significant enough to cause the document to be revised earlier than scheduled.

Prior to the work group convening to revise the document, ICSI members are asked to review the document and submit comments. During revision, a literature search of clinical trials, meta-analysis, and systematic reviews is performed and reviewed by the work group. The work group meets for 1-2 three-hour meetings to review the literature, respond to member organization comments, and revise the document as appropriate.

If there are changes or additions to the document that would be unfamiliar or unacceptable to member organizations, it is sent to members to review prior to going to the appropriate steering committee for approval.

Review and Comment Process

ICSI members are asked to review and submit comments for every guideline, order set, and protocol prior to the work group convening to revise the document.

The purpose of the Review and Comment process is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the order set and protocol. Review and Comment also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes needed across systems in their organization to implement the guideline.

All member organizations are encouraged to provide feedback on order sets and protocol, however responding to Review and Comment is not a criterion for continued membership within ICSI.

After the Review and Comment period, the work group reconvenes to review the comments and make changes as appropriate. The work group prepares a written response to all comments.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Notes from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI):

- For a description of what has changed since the previous version of this guidance, refer to "Summary of Changes Report -- October 2007."
- The recommendations for immunizations are presented in the form of immunization schedules and an algorithm with a total of 30 components accompanied by detailed annotations. Clinical highlights and immunization schedules are provided below for: *Immunization Schedule for Infants, Children, and Adolescents – Routine and High Risk* and *Immunization Schedule for Adults -- Routine and High Risk*. An algorithm for *In-Clinic Immunization* is provided in the original guideline document.
- There have been, and will be again in the future, shortages and delays in the distribution of many of the recommended vaccines. The situation varies by location and health care provider. The work group recommends that all practitioners be kept abreast of the latest national information on vaccine shortage by accessing the Centers for Disease Control and Prevention (CDC)'s Web site at http://www.cdc.gov/vaccines/news/default.htm.
- **December 2007 Addendum**: The Immunization Update is designed to provide current information and recommendations on Immunizations as released by the Centers for Disease Control that come in between the full revision of the guideline. The Immunization Update contains an immunization schedule as well as new or revised annotations to help the reader understand the options recommended for specific immunizations. This update provides revised recommendations for immunization against influenza for infants, children, and adolescents (routine and high-risk). Algorithm Annotation #9 in the original guideline document has been revised to reflect the new information, as well.

Clinical Highlights

- Utilize all clinical encounters as opportunities to assess a patient's immunization status. (*Annotation #17 - see the original guideline document*)
- Administer at each clinical encounter all immunizations that are due or overdue unless true contraindications exist. (*Annotations #20, 21, 26 - see the original guideline document*)
- Educate patients and parents regarding the importance of infant, childhood, adolescent, and adult immunizations, the recommended schedule and the need to maintain a personal record of immunizations and childhood diseases. (*Annotations #21, 23, 28 - see the original guideline document*)
- Document reasons for not administering immunizations that are clinically indicated, and flag the record for a recall appointment. (*Annotations #28, 29 - see the original guideline document*)
- Document the future plan for administering immunizations. (*Annotation #26, 28 - see the original guideline document*)

***Immunization Schedule for Infants, Children, and Adolescents – Routine and High Risk**

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	12 mos	15 mos	18 mos	24 mos	4-6 yrs	11-12 yrs	15-18 yrs
DTaP			X	X	X	X				X	Tdap	
IPV			X	X	X					X		

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	12 mos	15 mos	18 mos	24 mos	4-6 yrs	11-12 yrs	15-18 yrs
MMR (MMRV)	Combined measles, mumps, rubella and varicella vaccine (MMRV) is preferred for children 12 months through 12 years of age over separate injection of equivalent component vaccines.					X				X		
Varicella						X				X		X verify second dose completed
Pneumococcal (PCV7)			X	X	X	X						
Hib			X	X	X	X						
Rotavirus			X	X	X							
Hep B Schedule 1	X	X			X							
Hep B Schedule 2		X		X	X							
Influenza					X (6 to 59 months, annually)						X annually	X annually
Hep A						X	X					
Meningococcal											X	X if previously not received
Human Papilloma Virus (HPV)											X (3-dose series)	X (Catch up if appropriate, 3-dose series)

Abbreviations: DTaP, diphtheria, tetanus, acellular pertussis; Hep A, hepatitis A; Hep B, hepatitis B; Hib, *Haemophilus influenzae* type b; IPV, inactivated poliovirus vaccine; MMR, measles, mumps, and rubella; Tdap, tetanus-diphtheria-acellular pertussis; TIV, trivalent influenza vaccine.

*Please check manufacturer specifications for dosing, as all time intervals may not be needed.

For additional information on immunizing high-risk patients, see Annotation #14 in the original guideline document.

***Immunization Schedule for Adults -- Routine and High-Risk**

Vaccine	19-26 Years	27-39 Years	40-64 Years	65 Years and Older
Td/Tdap	Tdap if previously not immunized,			Td booster

Vaccine	19-26 Years	27-39 Years	40-64 Years	65 Years and Older
	Td booster every 10 years			
IPV	Immunize if not previously immunized			
MMR	Persons born during or after 1957 should have 1-dose measles; a second dose may be required in special circumstances (see Annotation #3 in the original guideline document).			
Varicella	X verify second dose completed	For all adults who do not have evidence of immunity to varicella, give two doses of varicella vaccine with at least 28 days between the first and second doses. (See Annotation #4 in the original guideline document.)		
Pneumococcal (PPV23)	Immunize high risk groups once. Re-immunize those at risk of losing immunity once after 5 years.			Immunize at 65 if not done previously. Re-immunize once if 1st received >5 years ago and before age 65 or an appropriate immunocompromising condition is present.
Hep B	Universal immunization		Immunize those at high risk.	
Influenza	Annually during flu season for individuals age 50 and older, those at high risk, and others.			
Hep A	Immunize those in risk groups			
Meningococcal	X	Immunize those in risk groups		
Human Papilloma Virus (HPV)	X Catch up, if appropriate,			
Herpes Zoster/Shingles				Immunize at age 60 and older

Abbreviations: Hep A, hepatitis A; Hep B, hepatitis B; IPV, inactivated polio vaccine; MMR, measles, mumps, rubella; Td, tetanus, diphtheria; Tdap, tetanus-diphtheria-acellular pertussis

*Please check manufacturer specifications for dosing, as all time intervals may not be needed.

For additional information on immunizing high-risk patients, see Annotation #14 in the original guideline document.

The Centers for Disease Control and Prevention (CDC) updates immunizations recommendations in January, July, and October -- please refer to the CDC website http://www.cdc.gov/vaccines/default.htm for the most current schedule.

CLINICAL ALGORITHM(S)

A detailed and annotated clinical algorithm titled "In-Clinic Immunization Algorithm" is provided in the original guideline document.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Increased rate of people on time with recommended immunizations
- Increased rate of special groups (pediatrics, adolescents, young adults, adults, seniors) on time with specific antigen immunizations
- Reduced missed opportunities for administering immunizations
- Increased rate of people who are not on time with recommended immunizations who have a catch-up plan
- Increased rate of post-immunization serologic testing for appropriate groups

POTENTIAL HARMS

- Adverse effects (i.e., local reactions, fever, mild forms of disease with attenuated formulations) specific to vaccines
- Caution should be exercised if Zostavax is administered to a nursing woman; pregnancy should be avoided for 3 months following vaccination with Zostavax
- A total of 15 confirmed cases of Guillain-Barre Syndrome (GBS) among individuals 11 to 19 years of age occurring within six weeks of vaccination with Menactra have been reported to the Vaccine Adverse Events Reporting System (VAERS). Two additional cases have been confirmed in persons 20 years of age and older. All individuals are reported to be recovering or have recovered.

  While the number of cases reported is at the edge of statistical significance and suggests a small increased risk of GBS following immunization with Menactra, the limitations in VAERS, and the uncertainty regarding background incidence rates for GBS require that these findings be viewed with caution.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Pregnancy is an absolute contraindication to varicella vaccination.
- Persons receiving 20 mg/day or more of prednisone or equivalent steroids for longer than two to three weeks should not receive live virus vaccines. Also, although data are limited, live virus vaccines would be contraindicated in persons on long-term tumor necrosis factor alpha inhibitor therapy and up to six months after completion of same. Persons with an underlying disease that

may suppress immune function who are also receiving corticosteroids should not receive live virus vaccines.
- Live bacterial (Bacillus of Calmette and Guerin [BCG], oral typhoid) and viral (CAIV-T, MMR, yellow fever, varicella) vaccines are contraindicated in patients with immunodeficiencies. BCG is also contraindicated in HIV-positive patients.
- Normal siblings of immunocompromised children should not receive live oral polio vaccine.

Zostavax® should not be administered to individuals with the following:

- A history of anaphylactic/anaphylactoid reaction to gelatin or neomycin
- A history of primary or acquired immunodeficiency states including leukemia; lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic system; or acquired immunodeficiency syndrome (AIDS) or other clinical manifestations of infection with human immunodeficiency viruses (see WARNINGS)
- Immunosuppressive therapy, including high-dose corticosteroids (over 20 mg/day for 3 months or longer)
- Active untreated tuberculosis
- Who are or may be pregnant
- Zostavax should not be used in children

Persons should not receive FluMist® if they:

- Have chronic heart disease
- Have chronic lung disease (including asthma and reactive airway disease)
- Have diabetes
- Have kidney failure
- Have illnesses that weaken the immune system
- Are taking medications that weaken the immune system
- Are children or adolescents receiving aspirin therapy
- Have a history of Guillain-Barre syndrome
- Are pregnant or lactating
- Have a history of allergy to eggs (or any vaccine component)

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This medical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.
- The Immunization work group realizes that the Centers for Disease Control and Prevention (CDC) updates immunization recommendations in January,

July and October. The CDC's Web site http://www.cdc.gov provides the most current schedule.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

Key Implementation Recommendations

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. Develop electronic data systems to track the immunization status of patients under the provider's care, with the capability to produce reminders and recalls of upcoming or overdue immunizations. (*Annotations #15, 29 - see the original guideline document*)
2. Remove barriers to immunization services. (*Annotations #15, 17 - see the original guideline document*)
3. Develop routine standing orders, to include specific criteria around immunizations that may be due at the current visit, and further stating that the immunization(s) may be given at any time during the visit. (*Annotations #15, 17 - see the original guideline document*)
4. Develop routine standing orders, to include specific criteria around immunization(s) that are overdue, stating that the overdue immunization(s) may be given to the patient at any time during the visit. (*Annotations #15, 28 - see the original guideline document*)
5. Provide staff training and education around routine standing orders in order to make it clear that routine standing orders are physician's orders that allow for administration of immunizations. Clearly define those staff who may administer these immunizations (registered nurse [RN], licensed practice

nurse [LPN], certified medical assistant (CMA), etc.). (*Annotation #15 - see the original guideline document*)
6. Develop tracking systems to produce periodic immunization audits for use in developing solutions to identified problems. (*Annotation #29- see the original guideline document*)

IMPLEMENTATION TOOLS

Clinical Algorithm
Pocket Guide/Reference Cards
Quality Measures

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED NQMC MEASURES

- Immunizations: percentage of two-year olds who are on time with their primary series of immunizations (DTaP, IPV, MMR, PCV7/PPV23, VZV, Hib, Hep B, Hep A, Rota).
- Immunizations: percentage of adolescents who are on time with recommended immunizations (Hep B, Hep A, HPV, MMR, MCV4, Tdap, VZV).
- Immunizations: percentage of young adults who are on time with Hepatitis B (Hep B).

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2007 Oct (addendum released 2007 Dec)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

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SOURCE(S) OF FUNDING

The following Minnesota health plans provide direct financial support: Blue Cross and Blue Shield of Minnesota, HealthPartners, Medica, Metropolitan Health Plan, PreferredOne and UCare Minnesota. In-kind support is provided by the Institute for Clinical Systems Improvement's (ICSI) members.

GUIDELINE COMMITTEE

Preventive Services Steering Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: James Nordin, MD (Work Group Leader) (HealthPartners Medical Group) (Pediatrics); Emma Carlin, MD (Park Nicollet Health Services) (Family Medicine); Barbara Yawn, MD (Olmsted Medical Center) (Family

Medicine); Lawrence Kerzner, MD (Hennepin County Medical Center) (Geriatrics); Lisa Moorhoorse, RN (Fairview Health Services) (Nursing); Barb Ottis, RN (Park Nicollet Health Services) (Nursing); Renner Anderson, MD (Park Nicollet Health Services) (Pediatrics); Robert Jacobson, MD (Mayo Clinic) (Pediatrics); Penny Fredrickson (Institute for Clinical Systems Improvement) (Implementation Advisor); Melissa Marshall, MBA (Institute for Clinical Systems Improvement) (Facilitator)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, Institute for Clinical Systems Improvement (ICSI) has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers. Readers of the guideline may assume that only work group members listed below have potential conflict of interest to disclose.

Dr. James Nordin negotiated research funds on behalf of HealthPartners Medical Group from Aventis Pasteur and Smith Kline Beecham.

Dr. Robert Jacobson negotiated research funds and was the principle investigator on behalf of Mayo Clinic from Novartis.

Dr. Lawrence Kerzner negotiated an educational grant on behalf of Hennepin County Medical Center from Merck.

Barbara Ottis, RN holds stock in Merck and Baxter.

Dr. Barbara Yawn negotiated research funds on behalf of Olmsted Medical Center from Merck.

No other work group members have potential conflicts of interest to disclose.

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GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version:

- Institute for Clinical Systems Improvement (ICSI). Immunizations update. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Sep. 4 p. [69 references]
- Institute for Clinical Systems Improvement (ICSI). Immunizations. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Jun. 61 p. [69 references]

- Institute for Clinical Systems Improvement (ICSI). Immunizations. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007 Jan. 8 p.

GUIDELINE AVAILABILITY

Electronic copies of the original guideline and the addendum: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Immunizations. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement, 2006 Jun. 1 p. Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.
- ICSI pocket guidelines. April 2006 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2006. 298 p.

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PATIENT RESOURCES

None available

NGC STATUS

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